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No. 10-453

In the
Supreme Court of the United States

APOTEX, INC.,
Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

On Petition for a Writ of Certiorari To The United States Court of Appeals For The District of Columbia Circuit

BRIEF OF AARP AND CONSUMER FEDERATION OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTERESTS OF *AMICI CURIAE*[1]

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010 at 2 (July 2000). Significantly, in a 2005 AARP survey, one in four Americans 50+ who took a prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, Ph.D., AARP, *Prescription Drug Use Among Midlife and Older Americans* (2005), *available at*

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[1] In accordance with Supreme Court Rule 37.6, *Amici Curiae* state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amici*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed of the intent to file this *amici* brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. *See e.g.,* AARP, Rx Watchdog Report, May 2010, *available at* http://www.aarp.org/health/drugs-supplements/rx_watchdog.html.

Consumer Federation of America ("CFA") is a non-profit organization founded in 1968 to advance consumer interests through research, education and advocacy. CFA is comprised of more than 280 state and local affiliates representing consumer, senior citizen, low income, labor, farm, public power and cooperative organizations. CFA represents consumer interests before federal and state regulatory and legislative agencies and participates in court proceedings. CFA has been particularly active on antitrust issues affecting health care, medical device, and high technology industries in which exclusive dealing and other practices by dominant firms can have significant consequences for consumers.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENT AND INTRODUCTION

Many patients face a daily struggle to pay for their prescribed medicines. This endangers their health and reduces their quality of life. When patients do not take prescribed medication because of cost, attendant health complications and the worsening of chronic disease stress the healthcare system as a whole.

The DC Circuit's decision below narrowly interpreting 21 U.S.C. § 355(j)(5)(D), the forfeiture provision of the 2003 Medicare Modernization Act amendments ("2003 MMA amendments") to the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), 21 U.S.C. §355 (1994), extends prescription drug market exclusivity, which in turn keeps the cost of prescription drugs artificially high in contravention to the purpose of the 2003 MMA amendments and the Hatch-Waxman Act.

For Hatch-Waxman and the MMA to provide the intended benefit to patients, there must be the correct balance of both incentives for generic challenges, and also open competition among generics. In this case the D.C. Circuit's decision is in sharp contrast with the language and purpose of the statute. The correct interpretation of the statute has a concrete impact on the health of patients and delayed resolution of this issue will result in

permanent harm to those patients in the form of increased medical cost and sub-optimal care. *Amici* therefore urge the Court to grant the Petition for *Writ of Certiorari* in this case.

ARGUMENT

I. THE DC CIRCUIT'S NARROW INTERPRETATION OF THE FORFEITURE PROVISION REDUCES GENERIC DRUG COMPETITION.

The forfeiture provision in the 2003 MMA amendments was not conceived merely as an elaborate method of determining privileges and priority among generic drug makers in a vacuum, but rather as a method to ensure the vitality of the generic drug industry, and increase competition among generic drug makers. Congress recognized that a thriving competition among generic drug makers drives down drug prices and improves the health care options available in the United States. *See* H.R. Rep. No. 98-857, pt.1 (1984), reprinted in 1984 U.S.C.C.A.N. 2647; *See also,* National Institute for Healthcare Management, A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace (June 2002). Hatch-Waxman and the 2003 MMA amendment were intended to speed generic entry into the market because the availability of generic drugs decreases the costs of medicine and allows more patients to get treatment. *See* 149 Cong. Rec. S15, 744-46 (daily ed. Nov. 24, 2003) (Sen. Schumer); 149 Cong. Rec. S15, 884 (daily ed. Nov. 25, 2003) (Sen. Kennedy).

While the D.C. Circuit raises the specter of a brand name drug undercutting the ability of a generic to earn exclusivity by the brand manufacturer's strategic withdrawal of a patent from the Orange Book, the record does not support such contrivance. Indeed, reported abuses to date have involved collusion between brand name and generic drug makers entering agreements to delay entry of generics. The FTC has reported extensively on "pay-for-delay" and generic drug "parking" of 180 day exclusivity as a way for the brand manufacturer and the first-to-file generic to reap monopoly/duopoly benefits. *See* FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010) (hereinafter "Pay-for-Delay"); *Competition in the Pharmaceutical Industry: Testimony before the S. Comm. on the Judiciary*, 108th Cong. (June 17, 2003) (statement of Timothy J. Muris, Chairman, FTC) *available at* http://www.ftc.gov/os/2003/06030617pharmtestimony.htm.

II. OPEN GENERIC DRUG COMPETITION AND LOWER PRICES AFFECT PATIENT OUTCOMES AND PUBLIC HEALTH.

A. Drug Prices Matter to Patient Outcomes.

For many patients, paying for their medicines is a daily struggle. For patients without insurance, the presence of a generic on the market may dictate whether they can afford treatment. Even for patients with insurance, the difference between a lower generic co-payment and a higher brand name

one affects the choices patients make. *See* Becky A. Briesacher, et al., *Patients At-Risk for Cost-Related Non-Adherence: A Review of the Literature*, 22 J. Gen. Internal Med. 864 (2007). For many older patients on multiple maintenance medications, even with insurance, co-payments can stress budgets pegged to a fixed income.

With no other choices available to them, many patients skip doses, split pills, and discontinue medications without consulting their physician, even in the case of serious illness. Jacob Kurlander, et al., *Cost-Related Non-Adherence to Medications Among Patients with Diabetes and Chronic Pain: Factors Beyond Finances*, 32 Diabetes Care 2143 (2009). The presence of a low-cost generic on the other hand may be the difference between a patient taking a prescribed medication, and that same patient skipping doses or choosing not to fill the prescription at all. *See Briesacher*, supra note 4 (finding that 32% of U.S. seniors took less medicine than prescribed because of cost, with reducing dosage more common than forgoing the prescription entirely.)

Patient compliance is a central issue in keeping hospital re-admissions down, reducing antibiotic resistance, and other serious health consequences. Studies of drug co-payment plans and drug pricing show that patients make cost-based decisions to forego treatment, even when facing acute infections for which antibiotics have been prescribed. This has been documented in both older patients and low-income patient populations. *See* Haim Reuveni, et

al., *The Effect of Drug Co-Payment Policy on the Purchase of Prescription Drugs for Children with Infections in the Community*, 62 Health Pol'y 1 (2002); Yuing Zhang, et al., *Ambulatory Antibiotic Use and Prescription Drug Coverage in Older Adults*, 170 Archives Internal Med. 1308 (2010).

Thus for both patients and public health systems, the cost of delayed generic access is twofold. First there is the increased cost of medication when open generic competition is not available. Second, non-adherence leads to medical complications that require advanced care, such as hospitalization. Diabetes presents one such case where proper medical management can prevent costly hospitalization, and even dialysis. *See* William Encinosa, et al., *Does Prescription Drug Adherence Reduce Hospitalizations and Costs? The Case of Diabetes*, 22 Advances Health Econ. Services Res. 151 (2010); *see also* Michael Soskol, et al., *Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost*, 42 Med. Care 521 (2005) (finding that the cost of medication adherence was "more than offset" by the reduced cost of disease-related medical costs). Towards this end, the price of medicines is vital to patients and public health. Further, high prices of medicines and medical care lead to other destructive practices such as medicine sharing and the over-use of emergency care.

B. Generic Drug Competition Dramatically Lowers Prices.

Open generic competition reliably drives down medicine prices. A Federal Trade Commission ("FTC") study on the effects of generic competition found that "in a mature generic market, generic prices are, on average 85% lower than pre-entry branded drug price." *Pay-for-Delay*, supra note 3 at 8. This is significant; the majority of generic savings come only when there is open competition. In the cases where there is only one generic, either as an authorized generic or through a Paragraph IV grant of exclusivity, a substantial price drop is rarely seen. A five year FDA study on the effect of generic competition on drug prices found that a sole generic entry into the market only reduced prices 6%, while the most aggressive competition yielded a 96% price reduction. The effect is seen as the number of generic entries increases, with more generic competition consistently yielding lower prices. FDA, *Generic Competition and Drug Prices, available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (last visited Nov. 1, 2010).

One hundred and eighty day exclusivity is a valuable tool to encourage brand competition, but there is a real price to pay. The decision to apply it is not, nor did Congress intend it to be, an absolute reward for a generic drug manufacturer when a forfeiture provision is triggered, as in the instant case.

III. RESOLVING THIS UNCERTAINTY IS URGENT BECAUSE OF THE HIGH NUMBER OF BLOCKBUSTER PATENT EXPIRATIONS EXPECTED IN THE NEAR FUTURE.

As discussed in the petition for *certiorari*, brand name medicines are often protected by multiple patents in the Orange Book. A given drug is usually protected not only by a core patent, but also by ancillary patents on methods of use, different isomeric forms, and variations such as extended release formulas. *See Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1374 (2002); 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006); and *see* Inderjit S. Bansal, et al., *Evergreening – A Controvercial Issue in Pharma Milieu*, 14 J. Intell. Prop. Rights 299, 301 (2009). Pharmaceutical companies use these ancillary patents to extend the term of protection for a drug beyond the twenty-year period contemplated by patent law.

Past complaints by the FTC against pharmaceutical manufacturers have included explicit allegations that manufacturers wrongfully listed patents in the Orange Book in order to block generic competition to their products. *See* Press release, Federal Trade Commission, Wrongful "Orange Book" Listing Raises Flag with FTC (April 23, 2002) *available at* http://www.ftc.gov/opa/2002/04/biovailtiazac.shtm ("acquiring an exclusive patent license and wrongfully listing that patent" in the "Orange Book" in order to "block[] generic competition to its branded drug..."). FTC testimony

in 2003 addressed the question of "whether certain 'later-listed' patents or inappropriate patent submissions by the sponsors of innovator drug products have resulted in the delay of generic drug approvals." *FTC Study: Generic Drug Entry Prior to Patent Expiration: Testimony before S. Comm. on the Judiciary*, 108th Cong. (June 17, 2003) (Daniel Troy, Chief Counsel, FDA). The FTC argued that pharmaceutical companies attempted to gain market monopoly through falsely asserting that a new patent exists "despite knowing that the patent does not, in fact, claim the drug." Memorandum for Federal Trade Commission as *Amicus Curiae* In Opposition to Defendant's Motion to Dismiss, *In re: Buspirone Patent Litigation*, 185 F.Supp.2d 363 (S.D.N.Y.) 2002, (No. 1410) ("In essence, BMS claims that a pharmaceutical company is at liberty, as a matter of antitrust law, to monopolize a market by means of falsely asserting to the FDA that a new patent claims its approved branded drug, despite knowing that the patent does not, in fact, claim the drug and hence does not meet the statutory criteria for listing in the Orange Book."). This strongly suggests that these ancillary patents are often of inferior quality and will not withstand judicial scrutiny. Supporting this conclusion, a 2002 study by the FTC showed that generic companies prevail in the strong majority of challenges under paragraph IV. *See* FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (July 2002) ("Generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute. The rate at which the U.S. Court of Appeals for the Federal Circuit reversed district court

decisions of patent invalidity and non-infringement for drug products in this study was 8 percent.").

Because these ancillary patents are used to extend the marketing exclusivity for a brand name drug, they are often the subject of paragraph IV challenges, and subject to withdrawal or delisting by the brand manufacturer near the end of a drug's market exclusivity.

In the immediate future, the industry faces an unprecedented number of patent expirations for blockbuster drugs currently prescribed to millions of patients. These conditions create heightened urgency to correctly interpret and apply the statutory scheme set out in the MMA and Hatch-Waxman.

GlaxoSmithKlein, AstraZeneca, Merck, and Pfizer, among others, will lose monopoly rights to at least one major drug before 2012. *See* Ben Hirschler, *Drugmakers face $140 bln patent "cliff"*, Reuters (May 1, 2007) *available at* http://www.reuters.com/article/idUSL01121531200705O2. By 2016, patent protection will expire on drugs accounting for $140 billion in sales. *See id.* This suggests that there will be an unprecedented number of challenges in the coming years by generic manufacturers attempting to acquire 180 days of exclusive access to the markets for these drugs. As consumers are about to reap the rewards of cheaper generic alternatives, it is critical that this issue be addressed to ensure that those consumers are not needlessly denied those benefits.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

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Respectfully submitted,

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